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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

HAMUD, FOZIA M

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 05/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

Office Action Summary

Application N .

09/830,967

Applicant(s)

CARCAGNO ET AL.

Examiner

Fozia M Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) 13 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other:

DETAILED ACTION

1. Claims 1-14 are pending and under consideration by the Examiner.

Priority

2. Should Applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign applications should be submitted under 37 CFR 1.55 in reply to this action.

Claim rejections-35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 3a Claims 2 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the host cell with the Accession number DSM ACC2397 is required to practice the claimed invention. As such the host cell must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If the host cell is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the host cell.

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The specification, provides an accession number for said host cell and states that the host cell was deposited on April 16, 1999 at DSMZ-Deutsche Sammlung von Mikroorganismen, (see page 23, lines 23-26), however, the specification lacks complete deposit information for the deposit of the host cell. If a deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that (a) during pendency of the application, access to the invention will be afforded to the Commissioner upon request, (b) all restrictions upon availability to the public will be irrevocable removed upon granting of the patent, (c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer, (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807) and (e) the deposit will be replaced if it should ever become inviable.

3b. Claim 4 recites "....wherein said vector comprises pVex 1.....", however, "pVex1" is not an art recognized vector. All of the vectors disclosed on page 12, lines 11-14 of

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the instant specification are art recognized, except for "pVex 1". Instant specification does not provide a description of the type of plasmid "pVex 1" is or how to obtain this vector. Therefore since the "pVex 1" recited in claim 4 is not described in the instant specification and since it is not art recognized and unavailable, one of ordinary skill in the art would not be able to practice the invention of claim 4. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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4a. Claims 1, 3, 5, 6, 7, 8, 9, 10, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over LinFu-Kuen Lin. (U.S Patent 5,618,698) in view of Jerry S. Powell (U.S Patent 5,688,679).

Lin teaches a host cell (COS, CHO cells), that is transfected with a vector that comprises a nucleotide sequence encoding human erythropoietin (EPO), SV40 promoter and terminator, said host cell which further comprises pDHFR vector, (see column 25, line 50 through column 26 line 37). The expression system used by Lin employed the selectable marker DHFR. In order to increase the quantity of EPO produced by cell strains having DHFR, Lin grew the host cells in the presence of methotrexate which inhibits the DHFR enzyme, (column 26, lines 38 through column 28, line 20).

However, Lin does not disclose a host cell comprising a vector which comprises a nucleotide sequence which encodes the polypeptide consisting of the amino acid sequence set forth in SEQ ID NO:1 as recited in the claims.

Powell teaches a host cell which comprises a nucleotide sequence which consists of a 2.4 kb Apal restriction fragment of genomic human erythropoietin gene, (see abstract and claims). Powell teaches that Apal restriction fragment of the human erythropoietin gene was selected to maximize efficient transcription of ertythropoietin RNA and effective translation and post-translation of the RNA into mature biologically active erythropoietin protein, (column 2, lines 19-25).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention, to modify the host cell taught by Lin, by transfecting it with

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a nucleotide sequence encoding the mature form of erythropoietin, because Powell teaches that using a fragment of erythropoietin gene which encodes only the mature protein yields large amounts of biologically active mature protein.

One of ordinary skill in the art would have been motivated to generate a host cell which produces mature form of erythropoietin, because erythropoietin regulates the level of oxygen in the blood by modulating the number of circulating erythrocytes and promotes the rapid growth of red cell progenitors in marrow, spleen and fetal liver, thus given the importance of erythropoietin, a method of producing large quantities of this hormone would have significant medical impact.

Conclusion

5. Claims 13 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4227 for regular communications and (703) 308-0294 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Fozia Hamud
Patent Examiner
Art Unit 1647
May 15, 2003


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